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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/880,573	06/13/2001	Shintaro Suzuki	27866/37501	8090

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EXAMINER

ROMEO, DAVID S

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 07/24/2003

41

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/880,573

Applicant(s)

SUZUKI, SHINTARO

Examiner

David S Romeo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-28 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 4-7, 8, 11-14, to the extent that they are drawn to a pc3 polynucleotide,
classified in class 536, subclass 23.5.
- II. Claims 2, 4-7, 9, 11-14, to the extent that they are drawn to a pc4 polynucleotide,
classified in class 536, subclass 23.5.
- III. Claims 3, 4-7, 10, 11-14, to the extent that they are drawn to a pc5 polynucleotide,
classified in class 536, subclass 23.5.
- IV. Claim 15, drawn to a pc3 polypeptide, classified in class 530, subclass 350.
- V. Claim 16, drawn to a pc4 polypeptide, classified in class 530, subclass 350.
- VI. Claim 17, drawn to a pc5 polypeptide, classified in class 530, subclass 350.
- VII. Claims 18, 21, 22, to the extent that they are drawn to a pc3 specific antibody,
classified in class 530, subclass 387.1.
- VIII. Claims 19, 21, 22, to the extent that they are drawn to a pc4 specific antibody,
classified in class 530, subclass 387.1.
- IX. Claims 20, 21, 22, to the extent that they are drawn to a pc5 specific antibody,
classified in class 530, subclass 387.1.
- X. Claim 23, drawn to a method comprising contacting a pc3 polypeptide with a pc3
specific antibody, classified in class 435, subclass 7.1.
- XI. Claim 24, drawn to a method comprising contacting a pc3 polypeptide with a pc3
peptide ligand, classified in class 436, subclass 501.

X. Claim 25, drawn to a method comprising contacting a pc4 polypeptide with a pc4 specific antibody, classified in class 435, subclass 7.1.

XI. Claim 26, drawn to a method comprising contacting a pc4 polypeptide with a pc4 peptide ligand, classified in class 436, subclass 501.

5 X. Claim 27, drawn to a method comprising contacting a pc5 polypeptide with a pc5 specific antibody, classified in class 435, subclass 7.1.

XI. Claim 28, drawn to a method comprising contacting a pc5 polypeptide with a pc5 peptide ligand, classified in class 436, subclass 501.

The inventions are distinct, each from the other because of the following reasons:

10 The polynucleotide of Invention I is related to the polypeptide of Invention IV by virtue of encoding same. The polynucleotide has utility for the recombinant production of the polypeptide in a host cell. Although the polynucleotide and polypeptide are related since the polynucleotide encodes the specifically claimed polypeptide, they are distinct inventions because they are physically and functionally distinct chemical entities, and the polypeptide product can
15 be made by another and materially different process, such as by synthetic polypeptide synthesis or purification from the natural source. Further, the polynucleotide may be used for processes other than the production of the polypeptide, such as a nucleic acid hybridization assay.

The polynucleotide of invention I and the antibody of Invention VII are related by virtue of the polypeptide that is encoded by the polynucleotide and necessary for the production of the
20 antibody. However, the polynucleotide itself is not necessary for antibody production and both are wholly different compounds having different compositions and functions. Therefore, these inventions are distinct.

The polypeptide of invention IV is related to the antibody of Invention VII by virtue of being the cognate antigen, necessary for the production of the antibody. Although the polypeptide and antibody are related due to the necessary steric complementarity of the two, they are distinct inventions because they are physically and functionally distinct chemical entities, and because the polypeptide can be used in another materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right, or in assays for the identification of agonists or antagonists.

The polynucleotide of Invention II is related to the polypeptide of Invention V by virtue of encoding same. The polynucleotide has utility for the recombinant production of the polypeptide in a host cell. Although the polynucleotide and polypeptide are related since the polynucleotide encodes the specifically claimed polypeptide, they are distinct inventions because they are physically and functionally distinct chemical entities, and the polypeptide product can be made by another and materially different process, such as by synthetic polypeptide synthesis or purification from the natural source. Further, the polynucleotide may be used for processes other than the production of the polypeptide, such as a nucleic acid hybridization assay.

The polynucleotide of invention II and the antibody of Invention VIII are related by virtue of the polypeptide that is encoded by the polynucleotide and necessary for the production of the antibody. However, the polynucleotide itself is not necessary for antibody production and both are wholly different compounds having different compositions and functions. Therefore, these inventions are distinct.

The polypeptide of invention V is related to the antibody of Invention VIII by virtue of being the cognate antigen, necessary for the production of the antibody. Although the

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polypeptide and antibody are related due to the necessary stearic complementarity of the two, they are distinct inventions because they are physically and functionally distinct chemical entities, and because the polypeptide can be used in another materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right, or

5 in assays for the identification of agonists or antagonists.

The polynucleotide of Invention III is related to the polypeptide of Invention VI by virtue of encoding same. The polynucleotide has utility for the recombinant production of the polypeptide in a host cell. Although the polynucleotide and polypeptide are related since the polynucleotide encodes the specifically claimed polypeptide, they are distinct inventions because

10 they are physically and functionally distinct chemical entities, and the polypeptide product can be made by another and materially different process, such as by synthetic polypeptide synthesis or purification form the natural source. Further, the polynucleotide may be used for processes other than the production of the polypeptide, such as a nucleic acid hybridization assay.

The polynucleotide of invention III and the antibody of Invention IX are related by virtue

15 of the polypeptide that is encoded by the polynucleotide and necessary for the production of the antibody. However, the polynucleotide itself is not necessary for antibody production and both are wholly different compounds having different compositions and functions. Therefore, these inventions are distinct.

The polypeptide of invention VI is related to the antibody of Invention IX by virtue of

20 being the cognate antigen, necessary for the production of the antibody. Although the polypeptide and antibody are related due to the necessary stearic complementarity of the two, they are distinct inventions because they are physically and functionally distinct chemical

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entities, and because the polypeptide can be used in another materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right, or in assays for the identification of agonists or antagonists.

The following pairwise combinations of products are independent and distinct, wherein
5 neither member of a pair is required for the production or use of the other, and wherein each of the pair can be manufactured independently of the other and used for independent and distinct purposes: I and each of II, III, IV, VI, VIII, IX; II and each of III, IV, VI, VII, IX; III and each of IV, V, VII, VIII; IV and each of V, VI, VIII, IX; V and each of VI, VII, IX; VI and each of VII, VIII; VII and each of VIII, IX; VIII and IX.

10 The following pairwise combinations of products and methods are independent and distinct, wherein the respective products may neither be produced by, nor used in the respective methods: I and each of X-XV; II and each of X-XV; III and each of X-XV; IV and each of XII-XV; V and each of X, XI, XIV, XV; VI and each of X-XIII; VII and each of XII-XV; VIII and each of X, XI, XIV, XV; IX and each of X-XIII.

15 Inventions IV and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case IV can be used in XI.

20 Inventions IV and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product

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as claimed can be used in a materially different process of using that product (MPEP
§ 806.05(h)). In the instant case IV can be used in X.

Inventions V and XII are related as product and process of use. The inventions can be
shown to be distinct if either or both of the following can be shown: (1) the process for using the
5 product as claimed can be practiced with another materially different product or (2) the product
as claimed can be used in a materially different process of using that product (MPEP
§ 806.05(h)). In the instant case V can be used in XIII.

Inventions V and XIII are related as product and process of use. The inventions can be
shown to be distinct if either or both of the following can be shown: (1) the process for using the
10 product as claimed can be practiced with another materially different product or (2) the product
as claimed can be used in a materially different process of using that product (MPEP
§ 806.05(h)). In the instant case V can be used in XII.

Inventions VI and XIV are related as product and process of use. The inventions can be
shown to be distinct if either or both of the following can be shown: (1) the process for using the
15 product as claimed can be practiced with another materially different product or (2) the product
as claimed can be used in a materially different process of using that product (MPEP
§ 806.05(h)). In the instant case V can be used in XV.

Inventions VI and XV are related as product and process of use. The inventions can be
shown to be distinct if either or both of the following can be shown: (1) the process for using the
20 product as claimed can be practiced with another materially different product or (2) the product
as claimed can be used in a materially different process of using that product (MPEP
§ 806.05(h)). In the instant case V can be used in XIV.

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The following pairwise combinations of methods are independent and distinct, wherein each member of a pair performs different functions, using different starting materials and/or process steps and/or with different outcomes: X and each of XI-XV; XI and each of XII-XV; XII and each of XIII-XV; XIII and each of XIV-XV; XIV and XV.

5 Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the searches required are not coextensive, restriction for examination purposes as indicated is proper.

10 Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR

15 1.143).

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M.

20 IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (703) 308-4623.

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE FOLLOWING TC 1600 BEFORE AND AFTER FINAL RIGHTFAX NUMBERS:

BEFORE FINAL (703) 872-9306

AFTER FINAL (703) 872-9307

25 IN ADDITION TO THE OFFICIAL RIGHTFAX NUMBERS ABOVE, THE TC 1600 FAX CENTER HAS THE FOLLOWING OFFICIAL FAX NUMBERS: (703) 305-3592, (703) 308-4242 AND (703) 305-3014.

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

30 FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (703) 308-0294.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

David Romeo
DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

35 JULY 23, 2003